IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PATTERSON A. GREEN, Plaintiff, v. JANSSEN PHARMACEUTICALS, INC., Defendant.	Civil Action No. 1:15-cv-00401-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before me are Defendant's Motion for Summary Judgment (D.I. 169), Defendant's Motion to Preclude Expert Testimony of Brendan Carroll, M.D. (D.I. 172), and Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan (D.I. 175). The Parties have fully briefed the issues. (D.I. 170, 173, 176, 191, 192, 193, 201, 203, 205). I heard oral argument on March 7, 2019. For the reasons set out below, I will grant Defendant's Motion for Summary Judgment and I will dismiss Defendant's *Daubert* motions as moot.

I. BACKGROUND

Plaintiff has struggled with severe mental illness throughout his life. (D.I. 192 at 6). He has been diagnosed with bipolar disorder, impulse control disorder, ADHD, post-traumatic stress disorder, and schizophrenia. (*Id.*). Doctors have prescribed him many medications, including Risperdal,[1] to treat these conditions. (*Id.*). Plaintiff was first prescribed Risperdal in March 2002 when he was seven years old. (*Id.*). He remained on the drug until 2007. (*Id.* at 6-7). Plaintiff also took an injectable form of Risperdal between November 2008 and December 2010. (D.I. 170 at 4). Plaintiff's Risperdal prescriptions came from at least ten different health care providers. (*Id.*). On April 3, 2008, Plaintiff was diagnosed with benign gynecomastia. (D.I. 192 at 7).

Risperdal is FDA-approved for treatment of schizophrenia and bipolar disorder. (D.I. 170 at 5). Defendant is the manufacturer of brand name Risperdal. (D.I. 192 at 1). Risperidone is the generic name for Risperdal. (D.I. 170 at 2).

Gynecomastia is a potential side effect of Risperdal. (D.I. 192 at 3-4). Increased levels of prolactin may also be a side effect and is allegedly connected to an increased risk of

[1] I use the brand name "Risperdal" to refer to the drug Plaintiff took. This is not meant to indicate whether Plaintiff took the brand name or a generic drug at any given time.

gynecomastia. (D.I. 176 at 8). Gynecomastia is the enlargement of the male breast gland due to a hormonal imbalance. Prolactin is a hormone which enhances breast development and initiates lactation in the human (typically female) body.

Plaintiff filed this lawsuit on May 19, 2015. (D.I. 3). He pled seven claims against Defendant based on its marketing and sale of Risperdal: negligence (Count I), negligent misrepresentation (Count II), breach of warranty (Count III), breach of the implied warranty of merchantability (Count IV), breach of the implied warranty of fitness for a particular purpose (Count V), breach of express warranty (Count VI), and fraud by concealment (Count VII). (D.I. 47 at 3-7). He alleges that because of Defendant's conduct, he experienced gynecomastia, weight gain, and suicidal thoughts and actions. (D.I. 170 at 5).

Defendant filed the present motions on October 12, 2018. It sought summary judgment on each count of the first amended complaint ("FAC"). (D.I. 47). In response to Defendant's summary judgment motion, Plaintiff voluntarily withdrew Counts III-VI. (D.I. 192 at 1 n.1). Plaintiff confirmed at oral argument that Count VII is also withdrawn. Thus, the only remaining Counts are negligence and negligent misrepresentation.

II. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the

moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247-49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

III. DISCUSSION

To succeed on a claim against Defendant, Plaintiff must overcome the learned intermediary doctrine. The doctrine is an exception to the general rule that a manufacturer owes a duty to directly warn a consumer of the risks associated with a product. *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399 (Del. 1989). Specifically, "a manufacturer of a prescription drug satisfies its duty to provide an appropriate warning about the drug when it gives the patient's

physician the necessary information to be disseminated to the patient." *Id.* (emphasis omitted). The doctrine is inapplicable if a warning is "inadequate as a matter of law." *Barba v. Carlson*, 2014 WL 1678246, at *2 (Del. Super. Ct. Apr. 8, 2014). Warnings are not inadequate as a matter of law if there is "a genuine issue of material fact about whether the warnings were adequate." *Id.* To maintain an action against a manufacturer when such a genuine factual dispute exists, a plaintiff must show that an additional warning would have made a difference to the plaintiff's treating physician. *Id.* at *3; *Barba v. Bos. Sci. Corp.*, 2015 WL 6336151, at *6 n.22 (Del. Super. Ct. Oct. 9, 2015) (clarifying that the inquiry employs a subjective test). This is because, if a more complete warning would not have made a difference to the prescriber, a plaintiff is unable to prove but for causation. *See Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014); *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008); *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991); *In re Plavix Mktg., Sales Practices & Prod. Liab. Litig.*, 2017 WL 4838842, at *6 (D.N.J. Oct. 26, 2017).

Plaintiff's factual allegations are insufficient to escape the application of the learned intermediary doctrine. Plaintiff argues, without citation to any legal authority, that the Risperdal label was inadequate as a matter of law, at least prior to October 2006. (D.I. 192 at 13). It is apparent from Plaintiff's summary of the evidence, however, that this is a genuinely disputed material fact. (*See id.* (identifying the deposition testimony of Carmen DeLoria, Janssen's Director of Business Development in Neuroscience, and the opinion of Dr. Mahyar Etminan, Plaintiff's labeling expert, as Plaintiff's evidence of inadequacy)). Plaintiff's evidence must be weighed by the factfinder against Defendant's expert's opinion that the Risperdal label adequately warns of gynecomastia, Defendant's expert's opinion that Plaintiff's labeling expert is not an authority on labeling, and the undisputed fact that Defendant's FDA-approved labels

warned of the risk of gynecomastia. (*See* D.I. 177-1, Exh. C at ¶¶ 42, 82 (Defendant's labeling expert, Dr. Arrowsmith, opining that "based on the available data and the regulations, the [Risperdal] package insert adequately and appropriately informed physicians of the essential prescribing information needed for safe and effective use" and "question[ing] Dr. Etminan's ability to comment on the adequacy of . . . Risperdal/risperidone labeling"); D.I. 174-1, Exh. A at 4 (March 2003 Risperdal label listing gynecomastia as "rare" adverse reaction); D.I. 204-1, Exh. 1 at 4, 7 (2006 label listing gynecomastia as adverse reaction to Risperdal); C.A. 16-135, D.I. 160-1, Exh. B at § 6.4 (2010 Risperdal label listing gynecomastia among potential adverse reactions)). Thus, Plaintiff has failed to establish that Defendant's warnings were inadequate as a matter of law.

Since Plaintiff cannot show inadequacy as a matter of law, Plaintiff must show that an additional warning would have made a difference to his prescribing physicians. Plaintiff cannot make such a showing. It is undisputed that only one of Plaintiff's ten prescribers was deposed for this litigation. (D.I. 170 at 4, 11). The physician who was deposed, Dr. Bowman, specifically testified that additional information on the risks associated with Risperdal would not have impacted his decision to prescribe Plaintiff the drug. (*Id.*). Plaintiff thus has no evidence that, but for the inadequate warning, he would not have been prescribed Risperdal. Thus, Defendant is shielded from liability by the learned intermediary doctrine. I will grant Defendant summary judgment on this basis.

IV. CONCLUSION

Plaintiff cannot establish a product liability cause of action against Defendant as he cannot establish that but for the allegedly inadequate warning he would not have taken Risperdal. Thus, I will grant Defendant's motion for summary judgment and enter judgment in favor of

Defendant. As no claims remain pending in the case, I will also dismiss Defendant's *Daubert* motions as moot.